SUMMARY OF THE
ON-SITE ASSESSMENT COMMITTEE MEETING
DECEMBER 15-16, 1999

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, December 15, 1999, at 1 p.m. Eastern Standard Time (EST) and on Thursday, December 16, 1999, at 8 a.m. EST as part of the Fifth NELAC Interim Meeting in Washington, DC. The meeting was led by its chair, Mr. Steven Baker of the Arizona Department of Health and by Mr. R. Wayne Davis of the South Carolina Department of Health and Environmental Control. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss issues outlined in the committee's previously distributed agenda.*

INTRODUCTION

The meeting began with a welcome by the facilitator, Mr. Owen Crankshaw. Mr. Crankshaw welcomed attendees, reviewed the meeting's ground rules, and explained his role as facilitator. The members of the committee introduced themselves. Mr. Baker then reviewed the afternoon's agenda.

ASSESSOR TRAINING COURSE DEVELOPMENT

Basic Training for NELAC Assessors

At Mr. Baker's request, Dr. Margot Hunt, U.S. Environmental Protection Agency (USEPA), updated those in attendance on the development of a basic NELAC assessor training course. The course has been developed under contract to USEPA by a private contractor who is experienced in the area of adult education but is not a scientist. Dr. Hunt pointed out that the Assessor Training Manual currently posted on the NELAC Internet site as a guidance document is written in compliance with 1998 NELAC Standards. She urged the committee to either drop or revise the manual. Mr. Baker explained that the purpose of the course is to ensure that all NELAC assessors are interpreting the NELAC Standards the same way. It will include an open-book final examination. The way the course will be presented (at multiple locations around the county, via regional satellite video conferencing, etc.) has not yet been formally decided. The question of who will approve the course has also not yet been decided. NELAC is a standard-setting body only and cannot approve the course. Ms. Jeanne Mourrain, NELAC Director, noted that she is currently meeting with NELAC attorneys to get clarification on this issue. Since the talks are not yet complete, Ms. Mourrain proposed that she meet with the On-site Assessment Committee in January 2000 to give them a full report.

Ms. Marlene Moore reviewed a proposal from the Global Institute of Environmental Scientists (GIES) to present a pilot training course to assessors from the first approved Accrediting Authorities (AAs). The two primary goals of the pilot course are to ensure that assessors from the first AAs are prepared to perform on-site assessments and to get feedback on the quality of the contractor-prepared course. After an initial survey of the AAs, GIES determined that at least one assessor from each of the approved AAs would attend a course presented in Washington,

DC. The state of California, however, would not be able to send all of its approximately 20 assessors to a Washington-based course. Consequently, the state of California has volunteered facilities if GIES will present a second course. Although GIES has assembled plenty of trainers and would probably be assured of plenty of attendees for two courses, GIES does not presently have sufficient funds to present two courses. Ms. Moore circulated GIES membership materials and noted that all membership fees collected in the next 60 days would be put toward the pilot course. She also noted that course attendees would be charged an attendance fee. No final decision has been made as to where the course or courses will be offered. USEPA Region 3 has offered the use of its Ft. Meade facility as an alternate East Coast training location. Ms. Moore anticipated that GIES would receive the course materials from USEPA in January 2000 and would offer the pilot course in late March or early April 2000.

Dr. Carl Kircher, of the Florida Department of Health, informed the committee that the state of Florida had recently presented its own five-day basic assessor training course. He reviewed for the committee his course materials and the manner in which they were presented. Course materials included a syllabus structured around the five-day outline presented in NELAC Standard Section 3.2 and a copy of the July 1999 NELAC Standards. Although a copy of the June 23, 1998, Assessor Training Manual was distributed to students in order to comply with the NELAC Standard Section 3.6.1, it was distributed with the caveat that it is based on an obsolete standard and was not used for training purposes. Florida's in-house course incorporated a take-home Quality Manual review and a second take-home exam designed to test the student's ability to provide thoughtful answers to questions for which the NELAC Standards provide no explicit answer. A multiple-choice final exam was offered either as 45-minute closed-book exam followed by a 30-minute open-book exam. Scores on the Quality Manual review ranged from 90% to 100%. All students provided thoughtful answers to the questions on the second take-home exam and were awarded scores of 100%. Scores on the multiple-choice final exam ranged from 50% to 90%. There was no statistical difference between scores on the open-book exam and scores on the closed-book exam. Dr. Kircher noted that students may tend to take more time to complete an open-book exam because they flip through the NELAC Standards looking for a specific passage. Dr. Kircher also noted that five days seems to be an appropriate time period in which to present the course.

Considerable discussion of assessor training issues ensued. Attendees expressed concerns about approval of training materials and training providers, consistency of interpretation of the NELAC Standards, and the use of the Assessor Training Manual currently posted on the NELAC Website. The committee acknowledged that the NELAC Standards will be revised. They expressed the hope that the first NELAC-trained assessors will give them feedback on areas in which the standards are not consistent so that the standards can be revised and these revisions can be included in refresher training.

Technical Training for NELAC Assessors

Mr. Baker noted that there is a four-year grandfathering period for technical training of assessors and suggested that training of assessors and consistency of assessments are essential to the success of the National Environmental Laboratory Accreditation Program (NELAP). He reviewed the committee's position on technical training courses. The committee envisions a

training program that will produce assessors who are experts in their fields of testing rather than "Jack-of-all-trades" assessors. Key elements of the committee's position on technical training course development are as follows:

- The technical course approach will be evenly split between data audit and systems audit.
- Courses for different disciplines will be developed independently of each other.
- Trainers will be technical experts in their respective disciplines. They will be drawn from private industry or government.
- Technical courses will include a final examination. The final examination will cover both data audit and systems audit and will include at least one data package.
- Data packages will be tailored to the course discipline.
- The final examination will be of such difficulty that qualified assessors will have no trouble passing the examination but individuals who are not qualified to assess certain fields of testing will be weeded out.
- Technical courses will be developed in at least the areas of microbiology, biotoxicity, asbestos analysis, radiochemistry (radchem), wet chemistry, organic chemistry, and inorganic chemistry.
- The On-site Assessment Committee proposes that certain prototype courses could be offered very quickly. A prototype microbiology course based on the Cincinnati EPA Environmental Monitoring and Support Laboratory (EMSL) drinking water microbiology course could be developed as soon as Fall 2000. An asbestos course could also be developed fairly quickly.
- The committee suggests that the organic chemistry course might take longer to develop due to the wide range of matrices (air, hazardous waste, drinking water, waste water, etc.) in which analyses are performed.

Mr. Baker noted that the On-site Assessment Committee would be focusing on development of technical training courses following the Fifth NELAC Interim Meeting and requested that attendees submit specific suggestions regarding course content to him in writing, preferably via e-mail. The committee asked for stakeholder input in prioritizing courses for development. The committee also asked for stakeholder input regarding how deeply an assessor must know the subject matter. There was considerable discussion of whether an assessor needs to know how to operate an instrument and perform a specific analysis or must only be trained in how to look at a data package to ensure that the Quality Systems (QS) are in place and deliver what they should deliver. The committee noted that the technical training courses assume a basic level of knowledge on the part of the student. They are not intended to teach an inexperienced individual how to perform an analysis. There was discussion of forensic audits to detect fraud versus routine audits to evaluate laboratory quality. Stakeholders from the commercial laboratory sector shared with the committee their experiences with on-site assessments. In response to questions about the committee's approach to refresher training, Mr. Baker commented that the committee has not yet addressed refresher training.

CHECKLIST DEVELOPMENT

Mr. Baker reviewed committee development of assessment checklists. The On-site Assessment Committee has wrestled with the issue of assessment checklists for three years. The committee has received input from numerous AAs, each requesting checklists in different formats or styles. In their December 7, 1999 meeting by teleconference, the On-site Assessment Committee agreed that they would be unable to develop assessment checklists that satisfy every AA and decided that the QS checklist prepared by Mr. Charles Dyer will be the only checklist prepared by the committee. AAs will be responsible for preparing other assessment checklists suited to their individual preferences. Mr. Dyer noted that the completed QS checklist has been posted on the NELAC Website in both WordPerfect® and Word® format. He explained his development of the checklist. The QS checklist has been developed to be consistent with the 1999 NELAC QS Standard with attempts to minimize the repetition of the NELAC QS Standard. AAs are free to change the order of the checklist so long as their checklist includes all items included in the NELAC QS Standard. In order to assure that AAs include all items included in the NELAC QS Standard, they will be required to submit a cross-reference between their prepared checklist and the NELAC QS Standard to the NELAP Director Ms. Mourrain. Although the decision of how to use the QS checklist rests with the AA, its use must be consistent with the NELAC Standards. Mr. Dyer noted that the On-site Assessment Committee plans no additional work on the QS checklist other than a yearly review and possible revision of the checklist to ensure that it is consistent with the current NELAC Standards. The committee then opened the issue to the floor for discussion.

An attendee noted that there had been discussion at the Fifth NELAC Annual Meeting of allowing assessors the option of sending the checklist in advance to the laboratory and using the laboratory's completed checklist in the on-site assessment. She asked if there had been additional discussion of this option. In response, the committee commented that this is just one of the many ways the checklist can be used by the AAs. Mr. Joe Slayton, chair of the NELAC QS Committee, noted that the QS Committee's first priority is feedback from the AAs on the use of the checklist. He encouraged the inclusion of a checklist column for laboratory document rather than a simple yes/no format in order to more easily record laboratory responses to the checklist items. Mr. Slayton encouraged the On-site Assessment Committee to support the use of technical checklists, specifically a checklist covering all the Quality Control (QC) items included in mandated test methods. He acknowledged that there are numerous mandated methods and suggested starting with just the USEPA mandated methods for drinking water and waste water. Mr. Slayton noted that he was not suggesting that the On-site Assessment Committee generate these checklists. He encouraged the committee to ask support of the USEPA's Office of Information Performance-Based Measurement Systems (PBMS) Workgroup to generate the checklists and to tell the On-site Assessment Committee what methods are thought to be procedurally defined. Mr. Slayton noted that the first step toward PBMS is to stress QC rather than procedural items. He also noted that such assistance from the USEPA PBMS Workgroup would show the agency's support of both PBMS and NELAC, and suggested that the On-site Assessment Committee clear the request with the NELAC Board of Directors before proceeding. Considerable discussion of this issue ensued. Mr. Baker noted that the On-site Assessment Committee has been given a directive from the board stipulating no method-specific checklists and suggested that the committee would have to receive a new directive from the board in order to proceed in that direction. There was also

considerable discussion of reciprocity and consistency in ranking the severity of deficiencies. An attendee suggested that assessors be given guidelines concerning the ranking of deficiencies in addition to standard assessment checklists. The committee noted that although all deficiencies must be addressed, specific decisions regarding critical deficiencies and corrective actions are the responsibility of the AA. Dr. Michael Miller, chair of the NELAC Regulatory Coordination Committee, noted that NELAC as a standard-setting body has no enforcement authority. The responsibility for enforcement rests with the AAs.

CHANGES TO THE NELAC STANDARDS

The committee requested stakeholder input on several issues that had been discussed in committee meetings (teleconferences). Mr. Davis led the discussion of the following issues:

- Issue of reciprocity arising from the question of whether an assessor must review all laboratory Standard Operating Procedures (SOP) or a statistical sample of the SOPs --

  Mr. Davis directed the audience's attention to Sections 3.4.2 and 3.6.1.g of the NELAC On-site Assessment Standard. While Section 3.4.2 states that, "The assessment...must cover all of the *tests* for which the laboratory seeks accreditation," Section 3.6.1 references "*test methods*." There was considerable discussion of whether a NELAC assessment report must reflect a review of every test method. Members of the committee pointed out that several states that are not NELAC AAs have indicated that they will accept NELAC assessment reports for reciprocity purposes. It was suggested that although it might not be necessary to review every laboratory SOP, the assessor should review consistency of SOPs across different test methods. It was also suggested that a review of a statistically representative number of SOPs penalizes small laboratories that have only a few SOPs. An attendee asked whether the On-site Assessment Standard allows assessors to add more deficiencies to their list after they leave the site. The committee answered in the affirmative and directed the attendee to Section 3.5.5. In explaining the justification for this section, the committee noted that a single assessor might not have time to formulate all deficiencies while on-site and suggested that it would behoove the laboratory to pay for additional assessor time on-site. The committee also noted that if different assessors on the same assessment team each review different items, then some deficiencies might not be identified until the assessors compare notes. No resolution was reached on this issue.

- Issue of "adequacy" of SOPs, including suggested clarification language --

  Mr. Davis directed the audience's attention to Section 3.6.1.g of the NELAC On-site Assessment Standard, which references the "*adequacy*" of the laboratory's SOPs and questioned how such adequacy might be assessed. He noted that the committee had considered clarification language suggesting that adequacy of SOPs may be defined by three elements: 1) that the laboratory has SOPs for all work performed in that laboratory, 2) that the SOPs are complete enough as to be repeatable, and 3) that the SOPs are consistent with the reference method. An attendee cautioned the committee against making revisions to the Standard without reviewing the interrelated sections of the On-site

Assessment Standard, including Section 3.5.3 addressing a minimum record set to be reviewed, Section 3.6.2 addressing the assessor's role and records review, and Section 3.6.4 addressing assessment standards. There was some discussion of whether the assessor must assess the SOPs against every laboratory test method and it was suggested that they assess the SOPs against only mandated test methods. No resolution was reached on this issue.

- Confidential Business Information (CBI) issues, including whether third-party assessors may sign CBI papers on behalf of the AA and whether non-government employees are held to the same accountability standards as government employees --

  It was noted that government employees may be subject to criminal penalties for the violation of CBI. The committee questioned what recourse is available to the laboratory if a third-party contract assessor violates CBI and suggested that the third-party assessor sign a confidentiality agreement with the laboratory. An attendee noted that the laboratory has the right to reject any third-party assessor if they have concerns regarding the release of trade secrets. No resolution was reached on this issue.

CONCLUSION

The committee thanked attendees for their input and encouraged the submission of other comments on the On-site Assessment Standard in written form. The allotted meeting time having expired, the committee meeting was adjourned at 11:30 a.m. EST.

Attachment A

ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE MEETING
DECEMBER 15-16, 1999

Item No.	Action	Date to be Completed
1.	Ms. Mourrain will meet with the On-site Assessment Committee to give them a full report of her meetings with NELAC attorneys regarding NELAC authority to approve assessor training courses and training providers.	1/31/00
2.	The On-site Assessment Committee will consider approaching the NELAC BoD for approval to ask support of the USEPA's Office of Information PBMS Workgroup in: 1) generating checklists covering all QC items included in USEPA mandated test methods for drinking water and waste water analysis, and 2) listing for the On-site Assessment Committee those methods thought to be procedurally defined.	1/31/00

Attachment B

PARTICIPANTS
ON-SITE ASSESSMENT COMMITTEE MEETING
DECEMBER 15-16, 1999

Name	Affiliation	Phone/Fax/E-mail
Baker, Steven Chair	AZ Dept of Health Svcs, Lab Lic. & Cert.	T: 602-255-3454 F: 602-255-3462 E: sbaker@hs.state.az.us
Buhl, Rosanna	Battelle Ocean Sciences	T: 781-952-5309 F: 781-934-2124 E: buhl@battelle.org
Davis, R. Wayne	SC Dept. of Health and Env Cntl	T: 803-935-7025 F: 803-935-6859 E: davisrw@columb36.dhec.state.sc.us
Davis, Susan (absent)	City of Austin	T: 512-927-4004 F: 512-927-4038 E: Susan.Davis@ci.austin.tx.us
Dyer, Charles	NH Dept of Environmental Services	T: 603-271-2991 F: 603-271-2867 E: c_dyer@des.state.nh.us
Friedman, David	USEPA/EMMC	T: 202-564-6662 F: 202-565-2432 E: friedman.david@epa.gov
Hall, Jack	Quanterra, Inc.	T: 423-588-6401 F: 423-584-4315 E: hallj@quanterra.com
Ingersoll, William	US Navy	T: 843-764-7337 F: 843-764-7360 E: IngersollWS@navsea.navy.mil
Moore, Marlene	Advanced Systems, Inc.	T: 302-834-9796 F: 302-995-1086 E: mmoore@advancedsys.com
Steinke, Athene	Severn Trent Laboratories (STL Baltimore)	T: 410-771-4920 F: 410-771-4407 E: asteinke@stl-inc.com
Finazzo, Barbara Ombudsman (absent)	USEPA Region 2	T: 732-321-6754 F: 732-321-4381 E: finazzo.barbara@epamail.epa.gov
Crankshaw, Owen (Contractor Support)	Research Triangle Institute	T: 919-541-7470 F: 919-541-7386 E: osc@rti.org
Greene, Lisa (Contractor Support)	Research Triangle Institute	T: 919-541-7483 F: 919-541-7386 E: lcg@rti.org